AMENDED IN ASSEMBLY MAY 4, 2015

AMENDED IN ASSEMBLY APRIL 7, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 339

Introduced by Assembly Member Gordon
(Coauthor: Assembly Member Atkins)

February 13, 2015

An act to add Section 1342.71 to the Health and Safety Code, and to add Section 10123.193 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 339, as amended, Gordon. Health care coverage: outpatient prescription drugs.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law requires a health care service plan or insurer that provides prescription drug benefits and maintains one or more drug formularies to make specified information regarding the formularies available to the public and other specified entities. Existing law also specifies requirements for those plans and insurers regarding coverage and cost sharing of specified prescription drugs.

This bill would require a health care service plan contract or a health insurance policy that is offered, renewed, or amended on or after January 1, 2016, and that provides coverage for outpatient prescription drugs,

to provide coverage for medically necessary prescription drugs, including those for which there is not a therapeutic equivalent. The bill would require copayments, coinsurance, and other cost sharing for these drugs to be reasonable, and would require that the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription not exceed $1/24$ of the annual out-of-pocket limit applicable to individual coverage for a supply of up to 30 days. The bill would require a plan contract or policy to cover single-tablet and extended release prescription drug regimens, unless the plan or insurer can demonstrate that multitablet and nonextended release drug regimens, respectively, are *clinically equally or* more effective, as specified. The bill would prohibit, except as specified, a plan contract or policy from placing prescription medications that treat a specific condition on the highest cost tiers of a drug formulary. The bill would require a plan contract or policy to use specified definitions for each tier of a drug formulary.

Because a willful violation of the bill's requirements relative to health care service plans would be a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 1342.71 is added to the Health and Safety Code, to read:

1342.71. (a) A health care service plan contract that is offered, amended, or renewed on or after January 1, 2016, shall comply with this section. This section shall not apply to Medi-Cal managed care contracts.

(b) (1) A health care service plan that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs.

(2) A health care service plan that provides coverage for outpatient prescription drugs shall cover a medically necessary prescription drug for which there is not a therapeutic equivalent.

(c) Copayments, coinsurance, and other cost sharing for outpatient prescription drugs shall be reasonable so as to allow access to medically necessary outpatient prescription drugs. The health care service plan shall demonstrate to the director that proposed cost sharing for a medically necessary prescription drug will not discourage medication adherence.

(d) Consistent with federal law and guidance, and notwithstanding Section 1342.7 and any regulations adopted pursuant to that section, a health care service plan that provides coverage for outpatient prescription drugs shall demonstrate ~~to the satisfaction of the director~~ that the formulary or formularies maintained by the health care service plan do not discourage the enrollment of individuals with health conditions and do not reduce the generosity of the benefit for enrollees with a particular condition.

(1) A health care service plan contract shall cover a single-tablet drug regimen that is as effective as a multitablet regimen unless the health care service plan is able to demonstrate to the ~~director that~~ *director,* consistent with clinical guidelines and peer-reviewed scientific and medical ~~literature~~ *literature,* that the multitablet regimen is clinically *equally or* more effective and more likely to result in adherence to a drug regimen. A health care service plan contract shall cover an extended release prescription drug that is clinically ~~as~~ *equally or more* effective ~~as~~ *than* a nonextended release product unless the health care service plan is able to demonstrate to the ~~director that~~ *director,* consistent with clinical guidelines and peer-reviewed scientific and medical ~~literature~~ *literature,* that the nonextended release product is clinically *equally or* more ~~effective.~~ *effective than the extended release product.*

(2) A health care service plan contract shall not place most or all of the prescription medications that treat a specific condition on the highest cost tiers of a formulary unless the health care service plan can demonstrate ~~to the satisfaction of the director~~ that such placement does not reduce the generosity of the benefits for enrollees with a particular condition. ~~In no instance in which there is more than one treatment that is the standard of care for a condition shall most or all prescription medications to treat that~~

~~condition be placed on the highest cost tiers.~~ *If there is more than one treatment that is the standard of care for a specific condition, the health care service plan shall not place most or all prescription medications that treat that condition on the highest cost tiers.* This shall not apply to any medication for which there is a therapeutic equivalent available on a lower cost tier.

(3) For coverage offered in the individual market, the health care service plan shall demonstrate ~~to the satisfaction of the director~~ that the formulary or formularies maintained for coverage in the individual market are the same or comparable to those maintained for coverage in the group market.

(4) A health care service plan shall demonstrate to the director that any limitation or utilization management is consistent with and based on clinical guidelines and peer-reviewed scientific and medical literature.

(e) With respect to an individual or group health care service plan contract subject to Section 1367.006, the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription shall not exceed ½₄ of the annual out-of-pocket limit applicable to individual coverage under Section 1367.006 for a supply of up to 30 days.

(f) (1) If a health care service plan contract maintains a drug formulary grouped into tiers, including a fourth tier or specialty tier, a health care service plan contract shall use the following definitions for each tier of the drug formulary:

(A) Tier one shall consist of preferred generic drugs and preferred brand name drugs if the cost to the health care service plan for a preferred brand name drug is comparable to those for generic drugs.

(B) Tier two shall consist of nonpreferred generic drugs, preferred brand name drugs, and any other drugs recommended by the health care service plan's pharmaceutical and therapeutics committee based on safety and efficacy and not solely based on the cost of the prescription drug.

(C) Tier three shall consist of nonpreferred brand name drugs that are recommended by the health care service plan's pharmaceutical and therapeutics committee based on safety and efficacy and not solely based on the cost of the prescription drug.

(D) Tier four shall consist of specialty drugs that are biologics, which, according to the federal Food and Drug Administration or the manufacturer, require distribution through a specialty pharmacy or the enrollee to have special training for self-administration or special monitoring. Specialty drugs may include prescription drugs that cost more than the Medicare Part D threshold if those drugs are recommended for Tier four by the health care service plan's pharmaceutical and therapeutics committee based on safety and efficacy, but placement shall not be solely based on the cost of the prescription drug.

(2) Nothing in this section shall be construed to require a health care service plan contract to include a fourth tier, but if a health care service plan contract includes a fourth tier, the health care service plan contract shall comply with this section.

(3) Nothing in this section shall be construed to require the health care service plan's pharmaceutical and therapeutics committee to consider the cost of the prescription drug to the health care service plan.

(g) A health care service plan contract shall ensure that the placement of prescription drugs on formulary tiers is not based solely on the cost of the prescription drug to the health care service plan, but is based on clinically indicated, reasonable medical management practices.

(h) Nothing in this section shall be construed to require or authorize a health care service plan that contracts with the State Department of Health Care Services to provide services to Medi-Cal beneficiaries to provide coverage for prescription drugs that are not required pursuant to those programs or contracts, or to limit or exclude any prescription drugs that are required by those programs or contracts.

SEC. 2. Section 10123.193 is added to the Insurance Code, to read:

10123.193. (a) A policy of health insurance that is offered, amended, or renewed on or after January 1, 2016, shall comply with this section.

(b) (1) A policy of health insurance that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs.

(2) A policy of health insurance that provides coverage for outpatient prescription drugs shall cover a medically necessary prescription drug for which there is not a therapeutic equivalent.

(c) Copayments, coinsurance, and other cost sharing for outpatient prescription drugs shall be reasonable so as to allow access to medically necessary outpatient prescription drugs. The health insurer shall demonstrate to the commissioner that proposed cost sharing for a medically necessary prescription drug will not discourage medication adherence.

(d) Consistent with federal law and guidance, a policy of health insurance that provides coverage for outpatient prescription drugs shall demonstrate ~~to the satisfaction of the commissioner~~ that the formulary or formularies maintained by the health insurer do not discourage the enrollment of individuals with health conditions and do not reduce the generosity of the benefit for insureds with a particular condition.

(1) A policy of health insurance shall cover a single-tablet drug regimen that is as effective as a multitablet regimen unless the health insurer is able to demonstrate to the ~~commissioner that~~ *commissioner,* consistent with clinical guidelines and peer-reviewed scientific and medical ~~literature~~ *literature,* that the multitablet regimen is clinically *equally or* more effective and more likely to result in adherence to a drug regimen. A policy of health insurance shall cover an extended release prescription drug that is clinically ~~as~~ *equally or more* effective ~~as~~ *than* a nonextended release product unless the health insurer is able to demonstrate to the ~~commissioner that~~ *commissioner,* consistent with clinical guidelines and peer-reviewed scientific and medical ~~literature~~ *literature,* that the nonextended release product is clinically *equally or* more ~~effective.~~ *effective than the extended release product.*

(2) A policy of health insurance shall not place most or all of the prescription medications that treat a specific condition on the highest cost tiers of a formulary unless the health insurer can demonstrate ~~to the satisfaction of the commissioner~~ that such placement does not reduce the generosity of the benefits for insureds with a particular condition. ~~In no instance in which there is more than one treatment that is the standard of care for a condition shall most or all prescription medications to treat that condition be placed on the highest cost tiers.~~ *If there is more than one treatment that is the standard of care for a specific condition,*

the health insurer shall not place most or all prescription medications that treat that condition on the highest cost tiers. This shall not apply to any medication for which there is a therapeutic equivalent available on a lower cost tier.

(3) For coverage offered in the individual market, the health insurer shall demonstrate ~~to the satisfaction of the commissioner~~ that the formulary or formularies maintained for coverage in the individual market are the same or comparable to those maintained for coverage in the group market.

(4) A health insurer shall demonstrate to the commissioner that any limitation or utilization management is consistent with and based on clinical guidelines and peer-reviewed scientific and medical literature.

(e) With respect to an individual or group policy of health insurance subject to Section 10112.28, the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription shall not exceed $\frac{1}{24}$ of the annual out-of-pocket limit applicable to individual coverage under Section 10112.28 for a supply of up to 30 days.

(f) (1) If a policy of health insurance maintains a drug formulary grouped into tiers, including a fourth tier or specialty tier, a policy of health insurance shall use the following definitions for each tier of the drug formulary:

(A) Tier one shall consist of preferred generic drugs and preferred brand name drugs if the cost to the health insurer for a preferred brand name drug is comparable to those for generic drugs.

(B) Tier two shall consist of nonpreferred generic drugs, preferred brand name drugs, and any other drugs recommended by the health insurer's pharmaceutical and therapeutics committee based on safety and efficacy and not solely based on the cost of the prescription drug.

(C) Tier three shall consist of nonpreferred brand name drugs that are recommended by the health insurer's pharmaceutical and therapeutics committee based on safety and efficacy and not solely based on the cost of the prescription drug.

(D) Tier four shall consist of specialty drugs that are biologics, which, according to the federal Food and Drug Administration or the manufacturer, require distribution through a specialty pharmacy or the insured to have special training for self-administration or

special monitoring. Specialty drugs may include prescription drugs that cost more than the Medicare Part D threshold if those drugs are recommended for Tier four by the health insurer's pharmaceutical and therapeutics committee based on safety and efficacy, but placement shall not be solely based on the cost of the prescription drug.

(2) Nothing in this section shall be construed to require a policy of health insurance to include a fourth tier, but if a policy of health insurance includes a fourth tier, the policy of health insurance shall comply with this section.

(3) Nothing in this section shall be construed to require the health insurer's pharmaceutical and therapeutics committee to consider the cost of the prescription drug to the health insurer.

(g) A policy of health insurance shall ensure that the placement of prescription drugs on formulary tiers is not based solely on the cost of the prescription drug to the health insurer, but is based on clinically indicated, reasonable medical management practices.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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